



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/662,918

09/15/2003

Sean B. Carroll

OPHD-08258

2733

23535 7590 07/17/2008

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

KIM, YUNSOO

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

07/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/662,918	Applicant(s) CARROLL ET AL.	
	Examiner YUNSOO KIM	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3-13 and 15-21 are pending and are being examined.
2. In light of Applicants' arguments filed on 4/16/08, the rejection set forth under 35 U.S.C. 2nd paragraph in the office action mailed 1/11/08 has been withdrawn.
3. The following rejections remain.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
5. Claims 1 and 3-13 stand rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 4,748,018 (IDS reference, of record), in view of Uemura et al. (Infection and Immunity, 1974, p. 470-471), of record, as is evidenced by Merck Manual of Diagnosis and Therapy (17th ed., 1999, p. 1176-1185), of record, for the reasons set forth in the office action mailed on 1/11/08.

Applicants' arguments filed on 4/16/08 have been fully considered but they were not found persuasive.

Applicants' traversal is based on that the combination of the references is not obvious. Applicants traversed the rejection based on that the '018 patent requires developing tolerance to the antibody by

virtue of having a history of consumption of the antibody while the claimed invention does not require developing tolerance. Moreover, the "consisting essentially of" phrase has been ignored.

Applicants further argued that the '018 patent does not teach *C. Perfringens* and Merck reference does not teach oral administration.

While Applicants differentiate the claimed invention from the reference based on the requirement of developing tolerance, the claimed invention is not limited to the method for administering an antibody to the population without developing the tolerance. Rather, the claimed invention is unpatentable over a combination of references that teach an oral administering of an avian antibody to *C. perfringens* solution in a subject. The combination of the '018 patent, Uemura and Merck reference does teach an oral administering of an avian antibody to *C. perfringens* solution in a subject. It is reminded that the obviousness rejection is based on a combination of the references and one cannot show unobviousness by attacking references individually.

In regards to the "consisting essentially of" phrase, it is true that MPEP 2111.03 indicates the "consisting essentially of" limits the claims to those steps specified and those steps that do not materially effect the basic novel characteristics of the claimed invention. However, in absent a clear indication the phrase is construed as equivalent to "comprising" (MPEP 2111.03). In the instant specification, there is no clear definition of "consisting essentially of" unlike Applicants assert. p. 6 of the instant specification discloses what encompasses the claimed invention (lines 13-22) but no indication of consisting essentially of.

Furthermore, Applicants argue that there is no motivation to combine the reference because the ordinary skilled in the art would use the antibiotics for infections and no one would use the time consuming antibody method as in the '018 patent. The Merck reference was provided to support the clostridial infections are mainly caused by the tetani, perfringens, or difficile species (p. 1176, of record). Moreover, the neutralization of toxins, antitoxin is used (p. 1178, of record, in particular). Further, antibiotic therapy is not the only method of treating the infections as is evidenced by the combination of references. Therefore, it is obvious to combine the references.

6. Claims 1, 5-8, 11-13, 15 and 18-20 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 4,689,299, of record, in view of U.S. Pat. No. 4,550,019, of record, for the reasons set forth in the office action mailed 1/11/08.

Applicants' arguments filed on 4/16/08 have been fully considered but they were not found persuasive.

Applicants' traversal is based on that the '299 patent teaches away the use of avian antibody because the '299 patent focuses on the use of monoclonal antibody and the limitation of claim 15 reciting "consisting of" has not been considered.

Even though the use of monoclonal antibody has advantages over the conventional polyclonal antibody in diagnostics which require more sensitive assays or in therapeutics, the addressed problems of polyclonal antibodies are not directed to avian antibodies. The problems associated with serum sickness upon treatment of tetanus with polyclonal antibodies and the allergic sensitivity are associated with horse antibodies. Rather, the avian antibodies are chemically and physically different from other mammalian conventional polyclonal antibodies (col. 3, lines 12-45, the '019 patent). The improvement of quality, specificity and avidity of the avian antibody is made over the conventional polyclonal antibody ('019 patent, col. 9-lines 23-64). Therefore, the use of avian antibody has advantage over conventional polyclonal antibody but also advantage over monoclonal antibody for more practical and convenient sources as taught by the '019 patent (col. 4, lines 46- col. 5, lines 34, in particular).

Moreover, claim 15 recites a method "consisting of". As discussed previously, the '299 patent teaches a method of administering a clostridium antibody orally (col. 16, lines 16-33) and the referenced method does not include or recite any other steps, the claimed method is included. Therefore, the combination of references remains obvious.

7. Claims 3, 4, 9, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,689,299, of record, U.S. Pat. No. 4,550,019, of record, as applied to claims 1, 5-8, 11-13, 15 and 18-20 above, and further in view of U.S. Pat. No. 4,748,018, of record, for the reasons set forth in the office action mailed 1/11/08.

Applicants' arguments filed on 4/16/08 have been fully considered but they were not found persuasive.

Applicants' traversal is based on that the '299 patent teaches away the use of avian antibody because the '299 patent focuses on the use of monoclonal antibody and the limitation of claim 15 reciting "consisting of" has not been considered and the combination of references is not obvious.

In light of the discussion above in section 6, the '299 patent does not teach away of using the avian antibody, therefore, the combination of references remains obvious.

8. No claims are allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim


Patent Examiner

Technology Center 1600

July 16, 2008

/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/662,918	CARROLL ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	